K033927 1/2

JAN 1 5 2004

510(K) SUMMARY
Arthroscopic Pump A115

I. Submitter's Name, Address, Telephone Number, Contact Person, Establishment Registration Number and Date Summary was Prepared:

W.O.M. WORLD OF MEDICINE AG
Alte Poststraße 11
96337 Ludwigsstadt
Germany

Phone number: 001 49 30 399 81 610
FAX number: 001 49 30 399 81 593

Establishment registration number: 8043980

Contact Person: Susanne Raab
368 North St. Asaph Street
Alexandria, VA 22314

Phone number : 703 299 0523
Fax number: 703 299 0523

Date Prepared : Dezember 9, 2003

II. Device Names:

1. Classification Name: Arthroscope and Accessories
2. Common or Usual Name: Arthroscopic Pump, Tubing Sets and Accessory
3. Proprietary Name: Arthroscopic Pump A115

III. Product Classification:

Product Code: HRX
C.F.R. Section: 21 C.F.R. § 888.1100
Device Class: II

IV. Predicate Devices:

- **Arthroscopy Pump A107** (K030402) manufactured by W.O.M. WORLD OF MEDICINE AG
- **Arthro-Surgimat- 2000 ECU** (K990443) manufactured by W.O.M. WORLD OF MEDICINE AG
- **Arthro-Surgimat-1500** (K983910) manufactured by W.O.M. WORLD OF MEDICINE AG

V. Intended Use:

The Arthroscopy Pump A115 is intended to provide fluid distention and irrigation of knee, shoulder, hip, elbow, ankle and wrist joint cavities during diagnostic and operative arthroscopic procedures.

VI. Device Description:

The Arthroscopy Pump A115 is a microprocessor controlled single roller pump designed to provide liquid distention and irrigation of joint cavities during diagnostic and operative arthroscopy. The pump functions according to the peristaltic principle. It consists of the following main components: a housing, a power supply, a roller wheel, a pump head, various setting keys and display elements. The device is to be used with special designed irrigation tubings, a remote control and foot pedal. A constant performed redundant pressure measurement controls the conformity of the actual pressure in the joint cavity with the pre-set nominal pressure.

VII. Substantial Equivalence:

The Arthroscopy Pump A115 described in this notification is similar in design and technological characteristics to the Arthroscopy Pump A107 (K030402), to the Arthro-Surgimat-2000 ECU (K990443) and Arthro-Surgimat-1500 (K983910) manufactured by W.O.M. WORLD OF MEDICINE AG. In addition, both the Arthroscopy Pump A115 and the predicate devices are intended to provide fluid distention and irrigation of knee, shoulder, hip, elbow, ankle and wrist joint cavities during diagnostic and operative arthroscopic procedures.

The differences between the Arthroscopy Pump A115 and the predicate devices are minor and raise no new questions of safety and effectiveness. Accordingly, W.O.M. WORLD OF MEDICINE AG believes that the Arthroscopy Pump A115 is substantially equivalent to the predicate devices currently on the market.

VIII. Performance/Clinical Data:

No performace or clinical data is provided.

IX. Voluntary Standards:

The device complies with the International Standard IEC 60601-1 (Electrical Safety) and IEC 60601-1-2 (Electromagnetic Compatibility) and bears the CE mark in accordance with the Medical Device Directive 93/42/EEC.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 5 2004

W.O.M. World of Medicine AG
c/o Ms. Susanne Raab
368 North Saint Asaph Street
Alexandria, Virginia 22314

Re: K033927
Trade/Device Name: Arthroscopy Pump A115
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope and accessories
Regulatory Class: II
Product Code: HRX
Dated: December 16, 2003
Received: December 18, 2003

Dear Ms. Raab:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATION FOR USE STATEMENT

510(k) Number (if known): K033927

Device Name: Arthroscopy Pump A115

Indications for Use:

The Arthroscopy Pump A115 is intended to provide fluid distention and irrigation of knee, shoulder, hip, elbow, ankle and wrist joint cavities during diagnostic and operative arthroscopic procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

(510(k) Number) K033927

Prescripition Use ✓ OR Over-The-Counter Use_____ (Per 21 C.F.R. 801.109)

(Optional Format 3-10-98)